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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,647	10/10/2000	Jeffrey M. Friedman	600-1-087CIP/DIV/COM	6790

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	8

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/686,647	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 October 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 7, 8 and 12, drawn to a nucleic acid sequence, vector and host cell, classified in class 435, subclass 320.1.

II. Claims 3-6, 9, 10, 13, 14, drawn to an isolated nucleic acid encoding an ob polypeptide, classified in class 536, subclass 23.1.

III. Claims 11, 15 and 16, drawn probes and primers classified in class 536, subclass 24.3.

IV. Claims 17-20, drawn to an ob polypeptide, classified in class 530, subclass 350.

V. Claims 21, 22 and 28-36, drawn to immunogenic peptide fragments, antibodies, classified in class 424, subclass 130.1+.

VI. Claims 37-48, drawn to methods and kits for screening ob polypeptides, classified in class 435, subclass 7.1.

VII. Claims 51-55, drawn to methods of reducing body weight and compositions therfore, classified in class 514, subclass 2.

VIII. Claims 56-58, drawn to methods of increasing body weight and compositions therfore, classified in class 435, subclass 320.1.

Claims 2 and 23-27 are generic to either group I or II and will be examined to the extent they read on the elected group.

Claims 49 and 50 are generic to either group VII or VIII and will be examined to the extent they read on the elected group.

The application contains claims directed to patentably distinct species of the claimed inventions (nucleic acids and polypeptides). The nucleotide sequences encoding different

proteins, probes, primers and nuclear localization sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C 121. Absent any evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C 121 and 37 CFR 1.141 et seq. Accordingly, only one (1) independent and distinct nucleotide or amino acid sequence will be examined in a single application without restriction.

The inventions are distinct each from the other because of the following reasons:

Inventions 1-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different inventions of group I-V are drawn to chemically distinct products with distinct functions and modes of operation. For example, the nucleic acids that encode a polypeptide have a distinct and different function from nucleic acids used as primers and probes. Collectively, the nucleic acids are different from the polypeptide products and ob polypeptide possesses different functions and modes of operation than antibodies directed to the ob polypeptides.

The inventions of groups VI-VIII are similarly distinct because the methods of screening for ob polypeptide have a different function (i.e. diagnostic) and effect from the methods of groups VII and VIII which are drawn to methods of decreasing or increasing body weight.

The products of groups I-III are unrelated to the methods of groups VI, VII and VIII because these methods do not rely upon the nucleic acids of groups I-III.

The products of group V are unrelated to the methods of group VII because the methods rely upon ob polypeptides not immunogenic fragments or antibodies. The products of group V are related to the methods of group VI and VIII as products and method of use; however because the methods may be carried out using materially different products, the inventions are distinct. For example, methods of increasing body weight may be carried out using anti-sense molecules instead of antibodies (both of which potentially reduce the activity of the ob polypeptide). The methods of screening for polypeptides can be carried out without antibodies; for example by using electrophoresis or northern blot analysis.

Finally, the products of group IV are unrelated to group VII s product and method of use. However, because the product can be used in other processes, such as the generation of antibodies, restriction between the groups is proper.

Because these inventions are distinct or the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches required for the different groups are not coextensive, restriction fro examination purposes as indicated is proper.

Applicants' representative, in a letter filed 7/14/02, elected without traverse in paper # 7 new claims 59-65 drawn to the invention of Group IV. Claims 1-58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see enclosed form PTO-948.

Figures 8, 11A and 12A are objected to under 37 CFR 1.83(a) because they fail to show any details as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because it exceeds the 250 words, limit. Correction is required. See MPEP § 608.01(b).

This application contains sequence disclosures that are encompassed by the definitions for nucleotides and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Specifically, there is a sequence listing disclosed on page 76 that does not have a SEQ ID number associated with it.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim reads on variant OB polypeptides in which amino acids in SEQ ID 2. 4. 5 and 6 are substituted with non-conservative amino acids. Applicant claims further read on the variant OB polypeptides having an N-terminal methionine or N-terminal polyaminoacid. Applicants do not provide a written description of said molecules.

The written description requirement for genus claims may be satisfied through sufficient description of a relevant a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics such as structure or other physical and/or chemical properties, by functional characteristics couple with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, applicants provide written disclosure of murine and human ob polypeptides, mature ob polypeptides (cleaved of the signal sequence) and murine and human ob polypeptides lacking a glutamine at

position 49 (SEQ ID numbers 2, 4, 5 and 6 and figures 1, 3, 5 and 6). Further disclosure provided for identification of new molecules claimed states "proteins displaying substantially equivalent or altered activity, including proteins modified deliberately, as for example, by site-directed mutagenesis, or accidentally through mutations in hosts that produce the modulators are likewise contemplated." Applicants provide neither written disclosure of claimed polypeptides nor relevant identifying characteristics of variant Ob polypeptides capable of modulating body weight in claimed invention. Inclusion of said claims is not supported by the specification and claims as originally filed. The instant application recites in claim 59 substitutions of amino acids in SEQ ID 2 or 4 of residues 53, 56, 71, 85, 89, 92, 95, 98, 110, 118, 121, 122, 126, 127, 128, 132, 139, 157, 159, 163 and 166 with non-conservative amino acids. In claim 60, applicant recites substitution of amino acids in SEQ ID 5 or 6 of residues 52, 55, 70, 84, 91, 94, 97, 109, 117, 120, 121, 125, 126, 127, 128, 131, 138, 156, 158, 162 and 165 with non-conservative amino acids. Applicants have not adequately pointed out where support for inclusion of substituted OB molecules, the specific amino acids and for non-conservative substitutions recited in the claim exists in the specification. Furthermore, claim 61 and 62 recite an OB polypeptide having an N-terminal methionine or an N-terminal polyaminoacid for which no support for inclusion is provided in the specification. It must be assumed that the skilled artisan would not conclude that applicant was in possession of claimed genus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kay Pinkney, patent analyst, whose telephone number is (703) 305-3553.

Maria B Marvich, PhD
Examiner
Art Unit 1636

July 29, 2002

DAVID GUZO
PRIMARY EXAMINER